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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,272	08/20/2004	Stephen Kerr	127272.00111	5520

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EXAMINER
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RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
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3773

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/505,272	<b>Applicant(s)</b> KERR, STEPHEN	
	<b>Examiner</b> MELISSA RYCKMAN	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 4/14/08.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5 and 7-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 7-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/3/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/14/08 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 5, 7-9 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hinchliffe (US 5586986).

Regarding Claim 1, Hinchliffe teaches a device for fashioning a closure of a puncture site in a tissue comprising: a cannula member (16) having proximal and distal ends and a lumen; a connecting rod (36) disposed axially within said cannula, said connecting rod having a proximal end oriented towards said proximal end of said cannula and a distal end oriented toward said distal end of said cannula, said connecting rod having an actuating mechanism (18) operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula a needle/suture complex (12, 14, 54) mounted upon said distal end of said connecting rod

(38), said needle/suture complex comprising at least one pair of angled needles (12, 14, it is noted that needles are angled relative to the needle holders, the cannula and comprise angled distal portions) having a suture extending there between (52) said needle/suture complex further comprising two or more needle holder arms (24, 26), said needle holder arms being angled (it is noted that the needle holder arms are angled with respect to the cannula, see fig. 7, and further are angled themselves, see fig. 7) and connected to the distal end (40) of said connecting rod (36), said connecting rod operative to pivot the needle holder arms between a first operative configuration wherein said needle holder arms extend in opposed directions from the distal end of said cannula (fig. 4), and a second operative configuration wherein said needle holder arms are biased inwardly relative to said first operative configuration (fig. 6); wherein said angled needles (12,14) are capable of transversing at least one tissue layer in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula (the device is capable of piercing the tissue as described); and a needle trap mechanism (46) disposed within the lumen of said cannula and operative to lockingly engage said needles (12, 14) of said needle/suture complex after said needle holder arms assume the second operative configuration (fig. 6); and wherein said needle trap mechanism is operative to draw said needles into the lumen of said cannula (fig. 6) such that the device may be withdrawn from the puncture site with the suture extending between the needles, forming a closure of said puncture site.

Regarding Claim 2, Hinchliffe teaches the device of claim 1, wherein said angled needles (12,14) are further operative to assume one or both of the following additional

configurations: a folded configuration wherein said angled needles are operative to extend through the lumen of said cannula (fig. 6), and a retracted wherein said angled needles are biased inwardly toward the lumen of said cannula (fig. 4).

Regarding Claim 3, Hinchliffe teaches the device of claim 2 wherein the distal end of said cannula (28) is positionable through a puncture site in a tissue (Column 4, proximate lines 19-25).

Regarding Claim 5, Hinchliffe teaches the device of claim 4 wherein each respective one of said pair of angled needles (12, 14) is operative to disengage from said needle holder arms after each needle holder arm transitions from its first operative configuration to its second operative configuration (fig. 7 to fig. 8).

Regarding Claim 7, Hinchliffe teaches the device of claim 1 wherein each respective one of said pair of angled needle holder arms (24, 26) are biased to extend across said puncture site as said needle holder arms assume said first operative configuration.

Regarding Claim 8, Hinchliffe teaches the device of claim 1 further comprising a handle formed upon said cannula (it is noted that any portion of the proximal end of the cannula, held by the user is a handle).

Regarding Claim 9, Hinchliffe teaches the device of claim 15, wherein said handle (proximal portion of cannula 16) and said trigger (18) are positioned relative one another to enable the handle to be grasped and the trigger to be manipulated by a single hand of a user.

Regarding Claim 13, Hinchliffe teaches the device of claim 1 further comprising a tapered mount (42 and 40) formed at said distal end of said connecting rod (36) wherein said needle/suture complex (12, 14, 54) is positioned upon (the complex is upon the tapered mount) said tapered mount (Fig. 7), said tapered mount having a generally hourglass shape (portions of 42 have a hourglass shape).

Regarding Claim 14, Hinchliffe teaches the device of claim 1 wherein said actuating mechanism is a trigger (18).

Regarding Claim 15, Hinchliffe teaches the device of claim 8 further comprising a trigger (18) formed on the proximal end of said connecting rod and operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula.

Regarding Claim 16, Hinchliffe teaches a device for fashioning a closure of a puncture site in a tissue comprising: a cannula member (16) having proximal and distal ends and a lumen; a connecting rod (36) disposed axially within said cannula, said connecting rod having a proximal end oriented towards said proximal end of said cannula and a distal end oriented toward said distal end of said cannula, said connecting rod having an actuating mechanism (18) operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula; two or more needle holder arms (24, 26), said needle holder arms being angled and connected to the distal end (42) of said connecting rod, said connecting rod operative to pivot the needle holder arms between a first operative configuration wherein said needle holder arms extend in opposed directions from the distal end of said cannula (fig. 4), and a

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second operative configuration wherein said needle holder arms are biased inwardly relative to said first operative configuration and into the lumen of said cannula (fig. 6); wherein said angled needles (12,14) are capable of transversing at least one tissue layer in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula (the device is capable of piercing the tissue as described); at least one pair of angled needles (12, 14) having a suture (52) extending therebetween; each of said angled needles mounted upon, respectively, each of said needle holder arms (fig. 4); and a needle trap mechanism (46) disposed within the lumen of said cannula and operative to lockingly engage said needles (12, 14) of said needle/suture complex after said needle holder arms assume the second operative configuration (fig. 6); and wherein said needle trap mechanism is operative to draw said needles into the lumen of said cannula such that the device may be withdrawn from the puncture site with the suture extending between the needles, forming a closure of said puncture site.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hinchliffe in view of Klein et al. (US 5860991)

Hinchliffe teaches all limitations of preceding dependent claims 1 and 2, and further teaches said needle catch (46) being operative to lockingly engage with said needles (12, 14) of said needle/suture complex after said needle assumes said second operative configuration (fig. 6), when lockingly engaged with said needle tips (12, 14) of said needles, disengages said needles from said needle holder and then captures said needles within said cannula but fails to teach wherein said needle trap mechanism comprises a cylindrical sleeve axially mounted about said connecting rod within said cannula, said needle trap mechanism having a proximal end with a lever formed thereon, and a distal end having a needle catch formed therein, wherein said lever formed upon said needle trap mechanism is operative to cause said needle trap mechanism to extend distally and retract proximally within the said cannula or wherein said needle trap mechanism.

Klein teaches a puncture closure device wherein said needle trap mechanism comprises a cylindrical sleeve (32) axially mounted about said connecting rod (14) within said cannula (s), said needle trap mechanism having a proximal end with a lever (16) formed thereon, and a distal end (fig. 9) having a needle catch (32) formed therein, said needle catch being operative to lockingly engage with said needles of said needle/suture complex after said needle assumes said second operative configuration, wherein said lever formed upon said needle trap mechanism is operative to cause said needle trap mechanism to extend distally and retract proximally within the said cannula (fig. 10 to fig. 11) and wherein said needle trap mechanism, when lockingly engaged with said needle tips of said needles, disengages said needles from said needle holder



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and then captures said needles within said cannula when said needle trap mechanism retracts proximally within said cannula (fig. 10 to fig. 11) in order to selectively move the needle trap mechanism with respect to the connecting rod such that the needle arms may be effectively disengaged from the needle holder without withdrawing the entire device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Hinchliffe with the needle trap mechanism of Klein in order to selectively move the needle trap mechanism with respect to the connecting rod such that the needle arms may be effectively disengaged from the needle holder without withdrawing the entire device.

### ***Response to Arguments***

Applicant's arguments filed 4/14/08 have been fully considered but they are not persuasive. The applicant generally argues the following:

- Hinchliffe does not have angled needles
- Hinchliffe does not have the angled needles capable of traversing at least one tissue layer in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula
- Hinchliffe fails to teach a first operative position
- Hinchliffe does not have sufficient space within the cannula to store the needles.

The examiner respectfully disagrees with the applicant, the needles of Hinchliffe are angled, the applicant argues that the needles are curved, the position of the examiner is that a curve is comprised of many angles. The distal portion of the needles clearly show an angle. When the needles goes through the motion of closing it does pass through at least one tissue layer in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula. There are many operative positions in Hinchliffe, when the needles arms as shown in Fig. 4 show the needle holder arms extend in opposed directions from the distal end of said cannula. The cannula of Hinchliffe would be modified with the needle trap of Klein as described above, Hinchliffe teaches an inner lumen, this would accommodate a needle trap.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR  
/Melissa Ryckman/  
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773